NATIONAL INSTITUTES OF HEALTH

NATIONAL ADVISORY ALLERGY AND INFECTIOUS DISEASES COUNCIL

MINUTES OF MEETING

May 23, 2005

The 150th meeting of the National Advisory Allergy and Infectious Diseases Council (NAAIDC) was convened at 10:30 a.m. on Monday, May 23, 2005, in Conference Room E1/E2, Building 45, National Institutes of Health. Dr. Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID) presided as Chairman.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public from 10:30 a.m. to 11:40 a.m. and from 1:00 p.m. to 5:00 p.m. The meeting was closed to the public from 8:30 a.m. to 10:30 a.m. and from 11:40 a.m. to 12:00 p.m. for review and consideration of individual grant applications. Notice of the meeting was published in the *Federal Register.*

Council Members Present:

Dr. Stanley Chapman
Dr. Charles Davis
Dr. Luis Diaz
Dr. Richard Insel
Dr. J. Brooks Jackson
Dr. Dorothy Lewis
Dr. Margaret Liu
Ms. Anne Munoz-Furlong
Dr. Martin Myers
Rev. Raymond O'Brien
Dr. Shelley Payne
Dr. Ruth Ruprecht
Dr. Gary Schoolnik
Dr. Gail Wertz

***Ex Officio* Members Present:**

Dr. Mitchell Cohen
Dr. Anthony Fauci

Council Members Absent:

Dr. Anthony D'Alessandro
Dr. Richard Locksley
Dr. Anjana Rao
Dr. Nathan Thielman

***Ex Officio* Members Absent:**

Dr. Lawrence Deyton

***Ad Hoc* Members:**

Dr. Jacques Banchereau
Dr. Barton Haynes
Dr. Megan Sykes

NIAID Senior Staff:

Dr. John McGowan
Dr. Carol Heilman
Dr. Daniel Rotrosen
Dr. Ed Tramont

Others Present:

Dr. Gary Nabel

I. REVIEW OF GRANT APPLICATIONS

The National Advisory Allergy and Infectious Diseases Council convened in closed session to consider applications in the areas of allergy and immunology, microbiology and infectious diseases, and AIDS.

Funding Actions: The Council reviewed 2,524 research and training applications with primary assignment to NIAID for a requested amount of $974,720,293 in first-year direct costs and recommended approval of 748 applications for $490,744,128 in first-year direct costs. One Method to Extend Research in Time (MERIT) award was recommended for approval.

II. REMARKS OF THE DIRECTOR, NIAID - Anthony S. Fauci, M.D.

Dr. Fauci opened the Council session by welcoming visitors to the meeting and noting that Drs. D'Alessandro, Locksley, Rao and Thielman would be absent. He introduced three *ad hoc* Council members: Dr. Jacques Banchereau, Baylor University; Dr. Barton Haynes, Duke University; and Dr. Megan Sykes, Massachusetts General Hospital. He also introduced Dr. Mitchell Cohen, Director of the Coordinating Center for Infectious Diseases, CDC. Dr. Cohen is replacing Dr. Jim Hughes as the *ex officio* member of Council from CDC.

Two of the *ex officio* members are no longer on the NIAID Advisory Council. Dr. Jim Hughes is moving from CDC to Emory University and Major General Lester Martinez-Lopez retired from the Army in April. The Department of Defense will recommend a new *ex officio* designee who should be at the next Council meeting in September.

Consideration of Minutes of Previous Meeting

The minutes of the January 24, 2005, meeting were considered and approved as written.

Staff and Organizational Changes

Dr. Fauci announced several staff changes in the Institute. Dr. Michael Kurilla has been appointed to the dual positions of associate director for biodefense product development in the Office of the Director and director of the Office of Biodefense Research Affairs in the Division of Microbiology and Infectious Diseases.

Dr. Charles Hackett has been appointed deputy director of the Division of Allergy, Immunology, and Transplantation.

In the Division of Microbiology and Infectious Diseases Dr. Linda Lambert was appointed chief of the Respiratory Diseases Branch, and Dr. B. Fenton "Lee" Hall was appointed chief of the Parasitology and International Programs Branch.

Dr. Fauci paid tribute to one of NIAID's stellar senior scientists, Dr. Frank Neva, who has been appointed scientist emeritus at NIAID.

Budget Update

Dr. Fauci recently accompanied Dr. Zerhouni to defend the President's FY 2006 budget request before the House and Senate Appropriations Subcommittees. The President's FY 2006 budget request for NIH is

$28.7 billion. This is an increase of $146 million or 0.5 percent over fiscal 2005. NIAID's proposed allocation for FY 2006 is $4.46 billion, an increase of $57 million or 1.3 percent over fiscal 2005. For the next step in the budget cycle, the President's budget request goes to Congress for review and action.

Legislative Update

Dr. Fauci reported that Congress is following the research activities of the Institute very closely, especially those related to biodefense and pandemic influenza. This is expected to continue as Congress plans to draft legislation to reauthorize NIH.

In February, Dr. Fauci testified at a congressional hearing about NIAID's progress in biodefense, including basic research, infrastructure, and the development of medical countermeasures. Dr. Fauci, along with Dr. Julie Gerberding, director, CDC, and Dr. Bruce Gellin, director, National Vaccine Program Office, testified before the House Appropriations Subcommittee's theme hearing on pandemic influenza.

Other briefings addressed HIV/AIDS and emerging infectious diseases research as well as the Institute's efforts to develop medical countermeasures to prevent and treat these diseases.

Drs. John McGowan, Carole Heilman, and Rona Hirschberg and Mr. Abe Mittelman participated in a briefing for the staff of the Alabama congressional delegation. Dr. Noel Rose briefed the American Autoimmune Related Diseases Association about the work of the Autoimmune Diseases Coordinating Committee.

Other Information Items

Dr. Fauci paid tribute to Dr. Maurice Hilleman, who passed away this year. Dr. Hilleman made major contributions to public health including developing eight of the 14 vaccines recommended for children and adults.

As a follow-up to his presentation at the January 2005 Council meeting, Dr. Fauci gave an update on the HIVNET 012 trial of single-dose nevirapine in preventing mother-to-infant transmission of HIV. The Institute of Medicine examined the trial and data and concluded, "The data are sound, presented in a balanced manner, and can be relied upon for scientific and policy-making purposes."

Another issue of importance to the Institute is women, girls, HIV and AIDS, the theme of World AIDS Day in December 2004. There is an extraordinary need for HIV prevention technologies that can be controlled by women, such as topical microbicides. In January 2005, an international trial to examine the safety and preliminary effectiveness of two candidate topical microbicides to prevent HIV infection opened to enrollment.

Dr. Fauci informed the group about a collaborative HIV vaccine study that NIAID is conducting with the Merck Company. He stressed the importance of the need to partner more closely with industry from the beginning of product development not only for HIV, but also in biodefense, influenza, and other areas.

He also updated the group on the development of the biocontainment facilities that will expand biodefense research capacity and highlighted the accomplishments and achievements in countermeasure development for smallpox, anthrax, Ebola, botulinum toxin, and influenza.

Dr. Fauci remarked on advances and research for West Nile virus, H5N1 influenza, and Marburg virus. He reemphasized that bioterrorism funds have been a benefit for public health, and the research being done will be applicable to fighting emerging and reemerging infections.

III. GUEST SPEAKER – Gary Nabel, M.D., Ph.D., Director, Vaccine Research Center, NIAID

Dr. Nabel stated that the major emphasis and effort in the Vaccine Research Center has been on HIV vaccines, but the Center has been called on to help as other problems have emerged. Other areas of focus include Ebola, Marburg virus, other hemorrhagic fevers, pandemic flu, SARS, and West Nile virus. The VRC starts with fundamental science in the laboratory and based on scientific discoveries, brings vaccine candidates forward.

The Center has 160 employees, a number expected to increase as two new laboratories open. Since 1998 its funding has increased in proportion to the NIH budget and is expected to level off with the rest of NIH. The first Board of Scientific Counselors review took place in February 2005. Five laboratories were reviewed, and the Board was very supportive of them all.

A few VRC investigators have made significant progress in their work, and Dr. Nabel gave a brief overview of their accomplishments. Peter Kwong was awarded a Presidential Early Career award, one of about ten in the nation, for his contributions to HIV envelope structure. The other major advance from Dr. Kwong's lab was the deduction of the V3 loop in the context of the native HIV envelope core. Dr. Mario Roederer recently published a paper showing that the memory of CD4 cells are selectively affected and nearly completely infected during a primary infection of SIV. Nancy Sullivan, a new independent investigator in the VRC, was involved in a study that defined the role of the cathepsin protease in activating the Ebola virus envelope for transduction of cells.

Dr. Nabel provided an update on HIV vaccine and biodefense-related products in clinical trials and the status of the pilot plant and the NIAID immune assessment lab. Finally, he gave an in-depth overview of the progress been made in clinical trials at the clinical trial center, ranging from the first DNA vaccine to the latest SARS and West Nile virus DNA vaccines.

IV. REPORT OF THE DIVISION OF ALLERGY, IMMUNOLOGY AND TRANSPLANTATION COUNCIL SUBCOMMITTEE - Daniel Rotrosen, M.D., Director

Dr. Rotrosen presented the following new staff members, scientific and division activities:

STAFFING/ORGANIZATIONAL CHANGES

Jui Shah, Ph.D., joined the Office of Clinical Applications in March 2005 as Senior Regulatory Affairs Officer. She received her doctoral degree in Pharmacology from the University of Houston and completed post-doctoral studies in the Department of Physiology at the University of Maryland. Prior to joining the Division, she was a Pharmacologist for the Center for Drug Evaluation and Research, at the Food and Drug Administration.

Steven Adah, Ph.D., joined the Office of Clinical Applications in March 2005 as Senior Regulatory Affairs Officer. He received his doctoral degree in Organic Chemistry from the University of Iowa and completed post-doctoral studies at the University of Tennessee and NIDDK, NIH. Prior to joining the Division he was a Product Reviewer for the Center for Drug Evaluation and Research at the Food and Drug Administration.

Alison Yao, Ph.D., joined the Office of the Director in May 2005 as a Program Officer for Bioinformatics. She received her Ph.D. in Molecular Genetics from the University of Guelph in Ontario, Canada, She did post doctoral training in plant genetics and six years experience in bioinformatics in private industry. Prior to joining the Division she was a Staff Scientist at Celera Genomics.

Ellen R. Rosenberg, R.N., B.S.N., M.A., joined the Office of Clinical Applications in February 2005 as a Nurse Consultant. Ms. Rosenberg received her bachelor's degree in Nursing from American University, District of Columbia. Prior to joining the Division, she was a Nurse Research Manager with the Medical Oncology Cancer Research Unit at the National Cancer Institute.

SCIENTIFIC INITIATIVES

Clinical Outcomes of Live Organ Donors RFA-AI-05-015: The National Institute of Allergy and Infectious Diseases (NIAID) and the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) invite applicants to participate in a program of epidemiologic research focusing on the medical and functional outcomes of individuals who have donated a kidney or a lobe of lung for transplantation into an individual with end-stage organ failure. This program will support a consortium consisting of clinical transplant centers and a Data Coordinating Center (DCC).

Cooperative Research Partnership for Biodefense RFA-AI-05-019: Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) and the Division of Allergy, Immunology and Transplantation (DAIT) support extramural research to control and prevent diseases caused by virtually all infectious agents. This includes basic biomedical research, such as studies of microbial physiology and antigenic structure; immunity; applied research, including the development of diagnostic tests; and clinical trials to evaluate experimental drugs and vaccines.

Genomics of Transplantation Cooperative Research Program RFA-AI-05-022: The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) invites applicants to participate in the expansion of the Genomics of Transplantation Cooperative Research Program for large-scale, broad-scope genomic studies in clinical transplantation, including solid organ, tissue, and cell transplantation. The original RFA (RFA-AI-04-002) was published in December 2003, and one cooperative research program project was funded in 2004. This RFA is a re-issuance of the previous RFA to expand the breadth of the cooperative research program in transplantation genomics. The long-term goal of the program is to understand the genetic basis of immune-mediated graft rejection and differences in transplant outcomes, and thereby provide a rational basis for the development of more effective treatment and prevention strategies to improve long-term graft survival and quality of life for transplant recipients. Applications are due September 16, 2005.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) to Improve The Chemistry and Targeted Delivery of RNAi Molecules PA-05-041: This funding opportunity will use the STTR (R41/R42) and SBIR (R43/R44) grant mechanism(s). Applications may be submitted for support as Phase I, Phase II or Fast-Track grants as described in the SBIR/STTR Omnibus Solicitation. Applicants may not simultaneously submit identical/essentially identical applications under both this funding opportunity and the SBIR/STTR Omnibus Solicitation.

DIVISION ACTIVITIES

American Association of Immunologists (AAI) Annual Meeting: The twenty-first annual Symposium on Contemporary Topics in Immunology, cosponsored by the NIAID and the AAI, was held as part of the Annual AAI Meeting that convened in San Diego, CA from April 2-6, 2005. This year's symposium included presentations on B cell activation, NKT cell ligands, T cell mediated killing, and antigen recognition and the immunological synapse. The NIAID and AAI also supported a presentation on NIAID-sponsored research networks and research resources. In addition, the NIAID sponsored a focus group meeting at the conference to discuss NIAID/NIH policies and issues of concern to basic and clinical research extramural investigators.

Biodosimetry: Current and Evolving Technologies Workshop: On February 28-March 1, 2005, the NIAID convened a workshop focused on the practical application of existing and emerging technologies in radiation biodosimetry to large-scale, civilian screening for radiation dose assessment following intentional or accidental radiation exposure. Topics presented included methods of biological and physical dosimetry, bioinformatics, genomics, proteomics, and devices under development.

Innate Immunity to Pathogen-Associated Molecular Patterns (PAMPs) of NIAID Category B Protozoa Workshop: On March 24, the NIAID convened a workshop focused on the identification of novel PAMPs and host pattern recognition molecules associated with Category B protozoa. Emphasis was placed on protozoan diseases, innate immunity in the gut, and how to apply innate immune response mechanisms to develop novel biodefense approaches against NIAID Category B protozoa.

Feasibility of Allogeneic Hematopoietic Stem Cell Transplantation for Autoimmune Diseases: On March 12-13, 2005, representatives of CIB, DAIT, NIAID, Experimental Transplantation and Immunology Branch, NCI, and Clinical Research Division, Fred Hutchinson Cancer Research Center, co-chaired an international workshop in Bethesda, co-sponsored by NIAID and NCI. The rationale for clinical trials of allogeneic hematopoietic cell transplantation in selected autoimmune diseases, with emphasis on subgroups of patients with multiple sclerosis and systemic sclerosis, and risk-benefit of transplantation regimens were discussed. A concise position paper with basic principles and guidelines for how such clinical trials should be pursued in the immediate future will be published.

Humanized Mouse Models: An Overview to Evaluate Opportunities and Set Priorities in the Context of Ongoing Trans-NIH Activities

Ad hoc Council members, guest, and division staff presented an interesting and stimulating discussion on humanized mouse models. Moderator and discussant Francesca Macchiarini, Ph.D., Division of Allergy, Immunology and Transplantation opened the discussion with an overview of NIAID's perspective and interest in **Humanized Mouse Models**; and Kristin Abraham, Ph.D., Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes & Digestive & Kidney Diseases, NIDDK also presented this Institute's perspective and interest in this particular topic. Leonard Shultz, Ph.D., Senior Staff Scientist, The Jackson Laboratories presented **Humanized SCID Mouse Models for Biomedical Research**. Jacques Banchereau, Ph.D., Director, Baylor Institute for Immunology Research discussed **Humouse: A Humanized Mouse to Develop Vaccines Against Categories A-C Agents**. Megan Sykes, M.D., Associate Director Transplantation Biology Research Center, Massachusetts General Hospital presented **Considerations on Thymic Origin in Humanized Mice**. And closing out the discussions, Malak Kotb, Ph.D., Professor, Surgery and Molecular Science, University of Tennessee, Department of Surgery presented the **Impact of Humanized Mice on Translational Research: Current Potential and Future Challenges**.

V. JOINT MEETING OF THE AIDS SUBCOMMITTEE, NATIONAL ADVISORY ALLERGY AND INFECTIOUS DISEASES COUNCIL AND AIDS RESEARCH ADVISORY COMMITTEE - Ed Tramont, M.D., Director, DAIDS

The AIDS Research Advisory Committee (ARAC) met on Monday, May 23, 2005, from 1:00 to 2:00 p.m., at the Natcher Conference Center on the NIH campus in Bethesda MD. Members participating: King Holmes (chair), Deborah Birx, Susan Buchbinder, Janet Collins, Charles Davis, Ashley Haase, Brooks Jackson, Jeffrey Lennox, Dorothy Lewis, David Margolis, Rev. Raymond O'Brien, Andrea Ruff and Ruth Ruprecht. NIAID staff participating in the meeting included: Drs. Tramont, Kagan, Dieffenbach, Fanning, Hafner, and Johnston and Mr. Daniel Montoya and Mr. Matthew Murguia. Ms. Rona Siskind served as Executive Secretary.

Director's Report

Dr. Tramont, DAIDS Director welcomed participants and announced that, because the agenda was light, the meeting would be conducted by videoconference, with seven members participating by telephone and webcast. Unfortunately, these technologies proved troublesome and led to the early termination of the meeting. Dr. Tramont acknowledged the service and contributions of two departing members, Moises Agosto and Andrea Ruff, whose terms will end in July. Dr. Holmes agreed to extend his term and will continue to chair ARAC for an additional year.

In updates on previous meetings, Dr. Tramont announced that the Panel on Clinical Practice will be established as a working group of the Office of AIDS Research Advisory Committee, rather than a working group of ARAC. Since the last ARAC meeting, four pre-application meetings for the Units for HIV/AIDS Clinical Trials Networks RFA were held in Bethesda, Miami, Johannesburg and Bangkok. The meetings were all well attended and the presentations as well as Q&A from workshops are posted on the DAIDS website at www.niaid.nih.gov/daids/rfa/network06/default.htm. A more detailed discussion of the external scientific review process that will be implemented in conjunction with the restructured Networks will be brought to the September meeting of the ARAC.

Concept Review: HIV-1 Proteins with Their Cellular Binding Partners

Dr. Carl Dieffenbach outlined the goals and structure of this proposed initiative, cosponsored by DAIDS and the National Institute of General Medical Studies (NIGMS). The objective is to foster collaborations between biochemists and structural biologists to define the interactions of HIV-1 proteins with their cognate host-cell partners and determine the three-dimensional structures of these complexes. The long-term goal is to understand the dynamics of HIV-1 protein containing complexes throughout the viral life cycle. The cooperative agreement would involve DAIDS, which would provide for the materials and services of the centers, which would be funded by NIGMS. The awards would be for 3-years, with first-year costs of $3 million.

This concept for a FY 2007 initiative was favorably reviewed. There were a few questions about institutional interactions, but overall, there was general agreement that it builds on the strengths of the respective Institutes. In the limited discussion that followed given technical difficulties, it was agreed that the program would accept proposals to study SIV interactions, as well as HIV. In essence, DAIDS would provide support to biochemists to investigate the interaction between a HIV protein and the target host protein. This would require analysis by a variety of methods. The resources of the NIGMS centers would be used to collaborate with the NIAID-supported investigators to advance the more interesting and biologically relevant protein pairs into structural analysis, ideally resulting in the determination of the 3D

structure of the complex. The committee also suggested that currently funded grantees with previously identified binding partner candidates be able to access the centers and collaborate. Additionally, the committee discussed and indicated that the projects should have a built-in milestone that allows for go-no go decisions. Further, funding should be ideally via milestone-driven grant applications, such as for the NIH Phased Innovation (R21/R33) Award.

Although the members present voted on the concept, those participating via conference were unable to participate in the voice vote due to technical difficulties. Those members faxed in their ballots and the concept received approval with the modification that the funding be based on a milestone driven mechanism such as the R21/R33.

Dr. Tramont was unable to present the scheduled DAIDS Portfolio Review due to technical difficulties and the meeting adjourned.

VI. REPORT OF THE DMID COUNCIL SUBCOMMITTEE - Carole A. Heilman, Ph.D., Director, DMID

Director's Report

Dr. Carole Heilman introduced Dr. Mitch Cohen, Director of the Coordinating Center for Infectious Diseases at CDC in Atlanta, who will serve as the Subcommittee's new *Ex Officio* member, and Dr. Barton Haynes, Director of the Human Vaccine Institute at Duke University and Principal Investigator of the Southeast Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research, who served as an *ad hoc* member for this Council meeting. She then asked the Branch Chiefs/Acting Branch Chiefs in attendance to introduce their own respective new hires.

Dr. Heilman then introduced DMID Deputy Director Dr. Pamela McInnes, who summarized the recently completed Gambia Pneumococcal Vaccine Trial, which NIAID helped support in conjunction with several other public and private partners. Dr. McInnes described this clinical trial as a "labor of love" for several staff members in DMID, who have been working on this study for more than 15 years. The vaccine was found to be highly efficacious and safe, and Dr. McInnes noted that the use of the multi-valent pneumococcal conjugate vaccine in developing countries could help achieve the UN Millennium Development Goal to reduce the under-five mortality rate by two-thirds by the year 2015.

Dr. Rona Hirschberg provided an update on NIAID's Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE) program, which is in its third year. She was accompanied by *ad hoc* Council member Barton Haynes, who oversees the Southeast RCE site. As background, Dr. Hirschberg reminded the Subcommittee that the original vision of this project was to have a program that would involve interdisciplinary teams or consortia of investigators at groups of institutions in a region, who could apply very broad approaches to problems in biodefense. These problems could span the range from basic to clinical, and would allow for flexibility and promote synergy with both local and regional cooperation and then coordination of the entire program at the national level. She then described how NIAID staff are managing the RCE program from an internal standpoint, spoke briefly about what the RCEs are doing and accomplishing, and noted that the program is already showing great signs of success. She reported that the Institute had issued a new RFA in April of 2004 for two more centers, which are expected to be funded in the near future. Dr. Haynes then spoke about the Duke University-based RCE, providing a site-specific perspective on the program. He discussed research accomplishments to date and plans and issues for the future. Current themes of the Southeastern RCE are

vaccine development, drug development, and host-defense immunology and vaccine adjuvant development.

Concepts

Following this discussion, DMID staff presented a number of concepts for the Subcommittee's review and approval, including:

Vaccine and Treatment Evaluation Units (VTEUs) – Dr. McInnes presented a concept to renew the VTEUs. For over 42 years, the VTEUs have been an important resource for vaccine and therapeutic research based on their contemporary research experience in Phase I/II studies, the ability to complete multisite projects, the availability of experienced research staff, access to large diverse populations, laboratory infrastructure and expertise with diagnostic assays. VTEU contracts provide the government with a mechanism to implement clinical research studies in an expeditious and efficient manner. Moreover, the VTEUs are able to engage in government directed research on short notice as occurred with the recent biodefense and influenza studies undertaken in a compressed time frame. During the past three years, a large percentage of the VTEU research effort has focused on biodefense projects. The Subcommittee wholeheartedly endorsed the renewal of this program.

DMID Regulatory Support Contract – Ms. Elizabeth Horigan presented the next concept, which would renew DMID's Regulatory Support Contract. This initiative will support a broad spectrum of regulatory activities, including data and document collection and compilation for regulatory filing for Investigational New Drug Applications (IND) with the US Food and Drug Administration (FDA). The Subcommittee unanimously approved the concept.

Tuberculosis Research Unit – This renewal initiative will support a consortium of TB investigators to conduct multidisciplinary, multinational research on host/pathogen interactions in TB to fill critical gaps in translational TB research and to provide tools needed to advance new health care interventions. The Subcommittee approved the concept.

Malaria Vaccine Production and Support Services - This project supports multiple aspects of preclinical development for candidate malaria vaccines. Although significant progress has been made under the current contract, additional candidate antigens need to be expressed for inclusion in multicomponent vaccines, additional platforms need to be evaluated in preclinical and clinical studies, and preclinical development work for a vaccine against *P. vivax* (the human malaria parasite with the widest geographic distribution) needs to be supported. The Subcommittee unanimously approved the concept.

Network on Antimicrobial Resistance in *Staphylococcus aureus* - This initiative will strengthen research on antibiotic resistance (AR) in *Staphylococcus aureus* by facilitating communications within the research community and providing research resources to multidisciplinary investigators and clinicians studying and treating AR in *S. aureus*. The concept was approved by the Subcommittee.

Clinical Trial for Community-Acquired Methicillin-Resistant *Staphylococcus aureus* Infections - Under this initiative, a clinical trial for treatment of CA-MRSA will be conducted. The optimal treatment of CA-MRSA infections will be validated with the goal of preventing the indiscriminate use of inappropriate antibiotics. It is hoped that the efficacy of off-patent antibiotics such as clindamycin or trimethoprim/sulfamethoxazole in treating CA-MRSA will be demonstrated. This initiative will focus on soft-tissue infections as it is the most common form of CA-MRSA infections. The Subcommittee unanimously approved the concept.

Clinical Laboratory Diagnostics for Invasive Aspergillosis - The purpose of this initiative is to evaluate contemporary diagnostics for invasive aspergillosis (IA). Under this initiative, appropriate clinical specimens (e.g., blood, bronchoalveolar lavage fluid) from patients at risk for IA will be analyzed using currently licensed as well as experimental laboratory tests for the purposes of diagnostic proof of principle and assay comparison. The Subcommittee unanimously approved the concept.

Assays for Influenza Therapeutics: Project BioShield – This initiative is designed to accelerate the development of therapeutic modalities directed against influenza by supporting research projects aimed at the establishment of rapid, high-throughput assays suitable for use in screening of libraries of chemical compounds. The Subcommittee approved the concept.

VII. ADJOURNMENT

The meeting of the Council was adjourned at 4:30 p.m., on Monday, May 23, 2005.

We do hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

Anthony S. Fauci, M.D. 08/29/2005
Chairman, National Advisory Allergy
and Infectious Diseases Council
Director, National Institute of Allergy
and Infectious Diseases

John J. McGowan, Ph.D. 08/19/2005
Executive Secretary
National Advisory Allergy and Infectious
Diseases Council
Director. Division of Extramural Activities
National Institute of Allergy and Infectious
Diseases

These minutes will be formally considered by the Council at its next meeting; any corrections or notations will be incorporated in the minutes at the meeting.